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From the INTERNATIONAL BUREAU

PCT	То:		
NOTIFICATION OF ELECTION (PCT Rule 61.2) Date of mailing (day/month/year) 05 January 2001 (05.01.01)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office		
International application No.	Applicant's or agent's file reference		
PCT/IB00/00310	088/01360		
International filing date (day/month/year) 20 March 2000 (20.03.00)	Priority date (day/month/year) 19 March 1999 (19.03.99)		
Applicant			
LOSHAKOVE, Amir et al			
The designated Office is hereby notified of its election made X in the demand filed with the International Preliminary	Examining Authority on: 00 (19.10.00)		
2. The election X was was not was not rnade before the expiration of 19 months from the priority d Rule 32.2(b).	ate or, where Rule 32 applies, within the time limit under		

Authorized officer

Telephone No.: (41-22) 338.83.38

Olivia TEFY

Form PCT/IB/331 (July 1992)

Facsimile No.: (41-22) 740.14.35

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

PCT

NOTIFICATION CONCERNING AMENDMENTS OF THE CLAIMS

(PCT Rule 62 and Administrative Instructions, Section 417)

Date of mailing (da	y/mon	th/year)
05 January	2001	(05.01.01)

International application No. PCT/IB00/00310

Applicant

BY-PASS, INC. et al

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

International filing date (day/month/year) 20 March 2000 (20.03.00)

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Olivia TEFY

Telephone No. (41-22) 338.83.38

Facsimile No. (41-22) 740.14.35

	From the INTERNATIONAL BUREAU			
PCT	To:			
NOTIFICATION OF THE RECORDING OF A CHANGE (PCT Rule 92bis.1 and Administrative Instructions, Section 422) Date of mailing (day/month/year)	FENSTER, Paul Fenster & Company Patent Attorneys, Ltd. P.O. Box 10256 49002 Petach Tikva ISRAËL			
20 September 2001 (20.09.01)				
Applicant's or agent's file reference 088/01360	IMPORTANT NOTIFICAT	FION		
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 March 2000 (20.03.00)			
The following indications appeared on record concerning:				
X the applicant X the inventor	the agent the common repr			
Name and Address LOSHAKOVE, Amir P.O. Box 204	IL ,	e of Residence		
42860 Moshav-Burgeta Israel	Telephone No.			
	Facsimile No.			
	Teleprinter No.			
2. The International Bureau hereby notifies the applicant that the the person the name X the add	ess the nationality th	ning: ne residence		
Name and Address	, ' l	e of Residence		
LOSHAKOVE, Amir P.O. Box 378		IL .		
60944 Moshav-Bazra Israel	Telephone No.			
	Facsimile No.			
	Teleprinter No.			
3. Further observations, if necessary:				
4. A copy of this notification has been sent to:				
X the receiving Office	the designated Offices concer	ned		
the International Searching Authority	X the elected Offices concerned			
X the International Preliminary Examining Authority	other:			
	Authorized officer	·		
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Elisabeth KÖNIG			
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38			

From the INTERNATIONAL SEARCHING AUTHORITY

To: FENSTER, PAUL . FENSTER & COMPANY PATENT ATTORNEYS, LTD.	PCT
PO BOX 10256 49002 PETACH TIKVA ISRAEL RECEIVED 0 4 -04- 2002	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION (PCT Rule 44.1)
FENSTER & Co.	Date of Mailing (day/month/year) 11 MAR 2002
Applicant's or agent's file reference 088/02281	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IL01/00600	International filing date (day/month/year) 28 JUNE 2001
Applicant BY-PASS, INC.	•
Filing of amendments and statement under Article The applicant is entitled, if he so wishes, to amend to When? The time limit for filing such amendment international search report; however, for Where? Directly to the International Bureau of Note that the search report is described by the search report in the search report; however, for the search report is described by the search report; however, for the search report is described by the search report; however, for the search report is described by the search report; however, for the search report is described by the search report in the search report is described by the search report in the search report is described by the search report in the search report is reminded of the search report in the search report is reminded of the following search report in the search report is reminded of the following search report in the search report is reminded of the following search report in the sea	he claims of the international application (see Rule 46): ents is normally 2 months from the date of transmittal of the more details, see the notes on the accompanying sheet. WIPO tes land 0.14.35 the accompanying sheet. Il search report will be established and that the declaration under n. additional fee(s) under Rule 40.2, the applicant is notified that: n has been transmitted to the International Bureau together with of both the protest and the decision thereon to the designated the applicant will be notified as soon as a decision is made. lowing: national application will be published by the International Bureau n, a notice of withdrawal of the international application, or of the s provided in rules 90 bis 1 and 90 bis 3, respectively, before the snal publication.
wishes to postpone the entry into the national phase u Within 20 months from the priority date, the applicant m	nternational preliminary examination must be filed if the applicant ntil 30 months from the priority date (in some Offices even later). The prescribed acts for entry into the national phase and in the demand or in a later election within 19 months from the not bound by Chapter II.

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

WILLIAM W. LEWIS Diane Smith for the property of the property of the property of the property of the ISA/US

Telephone No. (703) 308-0060

Form PCT/ISA/220 (July 1998)*

(See notes on accompanying sheet)

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/02281	FOR FURTHER ACTION	(Form PCT/ISA/29	Transinittal of International Search Report 20) as well as, where applicable, item 5 below.			
International application No.	International filing da	te (day/month/year)	(Earliest) Priority Date (day/month/year)			
PCT/IL01/00600	28 JUNE 2001		11 DECEMBER 2000			
Applicant BY-PASS, INC.						
according to Article 18. A copy is being	transmitted to the Inter	national Bureau.	thority and is transmitted to the applicant			
This international search report consist	s of a total of <u></u> sheet	ss.				
X It is also accompanied by a co			eport.			
Basis of the report a. With regard to the language, the	e international search was	s carried out on the b	asis of the international application in the			
language in which it was filed,	unless otherwise indicated	d under this item.	e international application furnished to this			
- ` ` ' ''	and/or amino acid seque the sequence listing:	ence disclosed in the	international application, the international search			
contained in the internationa		form.				
filed together with the inters	national application in co	mputer readable forr	n.			
furnished subsequently to thi		•				
furnished subsequently to thi	s Authority in computer	readable form.				
the statement that the subs	the statement that the subsequently furnished written sequence listing does not go beyond the disclosure					
the statement that the informat furnished.	ion recorded in computer i	readable form is identi	cal to the written sequence listing has been			
2 Certain claims were found	unsearchable (See Box 1	I).				
3. Unity of invention is lackin	g (See Box II).	•				
4. With regard to the title,						
x the text is approved as subm	nitted by the applicant.					
the text has been established	by this Authority to rea	ad as follows:				
5. With regard to the abstract,						
the text is approved as subm	itted by the applicant.					
the text has been established Box III. The applicant may, v search report, submit comme	, according to Rule 38.2(vithin one month from th	b), by this Authority e date of mailing of t	as it appears in his international			
6. The figure of the drawings to be pul	olished with the abstract	is Figure No. 2A	_			
X as suggested by the applican	t.		None of the Comme			
because the applicant failed t	o suggest a figure.		None of the figures.			
because this figure better cha						

International application No. PCT/IL01/00600

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

Abstract of the Disclosure

Hole forming apparatus (100) for forming an opening in a blood vessel (106) comprising a penetration head (104) for insertion through a wall of a blood vessel (106). The apparatus (100) has a base section (102) and at least one cutting surface (114) on at least one of the base section (102) or the penetration head (104). The cutting surface (114) is adapted to contact first an intima surface of the blood vessel (106). The apparatus (100) further has a shaft operatively connected to the cutting surface (114) and configured to rotate the cutting surface (114) relative to the blood vessel (106), while the penetration head (104) and the base section (102) are brought together, to effect a removal of a plug tissue section from the blood vessel (106).

International application No. PCT/IL01/00600

A. CLA	ASSIFICATION OF SUBJECT MATTER		
IPC(7)	:A61B 17/32		
US CL	:606/185		
According	to International Patent Classification (IPC) or to be	oth national classification and IPC	
B. FIE	LDS SEARCHED		
Minimum	documentation searched (classification system follow	red by classification symbols)	
U.S. :	606/1, 108, 159, 181-185	by committee on symbols,	
Documenta	ation searched other than minimum documentation	to the extent that much d	
searched	documentation	to the extent that such documents are	included in the fields
Flectronic	data hase consulted during the interestical and	(
	data base consulted during the international search	(name of data base and, where practicable	e, search terms used)
none			
			·
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT		<u>-</u>
	TO BE RELEVANT		
Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.
			`
Y	US 5,827,316 A (YOUNG et al.)	27 October 1998, see entire	1-50
	document.		
i		ļ	
\mathbf{Y}_{\perp}	US 5,910,153 A (MAYENBERGER	R) 08 June 1999, see entire	1-50
	document.	,	
		·	•
Y	US 6,022,367 A (SHERTS) 08 Februa	ry 2000, see entire document	1-50
	, , , , , , , , , , , , , , , , , , , ,	ay 2000, see chare document.	1-30
	·		
	·	·	
Furth	ner documents are listed in the continuation of Box	C. See patent family annex.	
• Spe	ecial categories of cited documents:	"T" later document published after the inter	enutional filing date or priority
"A" doc	rument defining the general state of the art which is not	date and not in conflict with the applie the principle or theory underlying the	cation but cited to understand
	nsidered to be of particular relevance		
	fier document published on or after the international filing date	considered novel or cannot be consider	ed to involve an inventive step
cite	cument which may throw doubts on priority claim(s) or which is ad to establish the publication date of another citation or other	when the document is taken alone	
spe	cial reason (as specified)	"Y" document of particular relevance; the considered to involve an inventive	claimed invention cannot be step when the document is
"O" doc mea	nument referring to an oral disclosure, use, exhibition or other	combined with one or more other such being obvious to a person skilled in th	documents, such combination
"P" doc	ument published prior to the international filing date but later	- •	
tha	n the priority date claimed	The second of the second parent	
Date of the actual completion of the international search Date of mailing of the international search report			
30 DECEMBER 2001 11 MAR 2002			
Name and m Commission	Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Authorized officer		
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20251 WILLIAM W. LEWIS Diane Smith			
Facsimile No		Telephone No. (709) 808 0000	e pinery

International application No. PCT/IL01/00267

A. CL.	ASSIFICATION OF SUBJECT MATTER	
US CL	:A61B 17/08 :606/153	
According	to International Patent Classification (IPC) or to both national classification and IP	C
B. FIE	ELDS SEARCHED	
Minimum	documentation searched (classification system followed by classification symbols)	
U.S. :	606/153-155, 99, 104, 108, 184-186; 600/567	
Documenta	ation searched other than minimum documentation to the extent that such docume	nts are included in the follow
searched		and the included in the fields
Electronic	data base consulted during the international search (name of data base and, where pr	racticable, search terms used)
Di	ns n	ĺ
	rms: sheath, slot, spike, punch, guidewire, serrated	·
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT	
		· .
Category*	Citation of document, with indication, where appropriate, of the relevant passa	ges Relevant to claim No.
X	US 4,696,308 A (MELLER et al.) 29 September 1987, see e	entire 20,24-29,
·	document.	34-37,43
Y		
		21-23.
		30-33
Χ -	US 5,201,901 A (HARADA et al.) 13 April 1993, see e document.	entire 44,46
A A,P	US 5,234,447 A (KASTER et al.), 10 August 1993, see e document.	
`, '	US 6,193,734 B1 (BOLDUC et al.) 27 February 2001, see e document.	entire 1-19
A	US 5,823,971 A (ROBINSON et al.) 20 October 1998, fig. 2.	62-63
Furth	ner documents are listed in the continuation of Box C. See patent family an	
Бре	cial catagories of cited documents:	
	amount defining the general state of the art which is not considered date and not in conflict with the principle or theory under	or the international filing date or priority to the application but cited to understand rlying the invention
a docu	tior document published on or after the international filing date "X" document of particular rele considered novel or cannot be	vance; the claimed invention cannot be
	d to establish the publication date of another citation or other	2000
	amont referring to an oral disalars.	vance; the claimed invention cannot be ntive step when the document is combined
	with one or more other and	on ancaments, such combination being
doen mea doen than	obvious to a person skilled in ament published prior to the international filing date but later "&" document member of the sam	the art
doen mea doen than	obvious to a person skilled in ament published prior to the international filing date but later "&" document member of the same appropriate to the priority date claimed.	ne patent family
docu mea docu than ate of the a	amount published prior to the international filing date but later and document member of the same actual completion of the international search. Date of mailing of the international search.	ne patent family
does does does than ate of the a way SEPTE. The same and machine and commissione Box PCT	amount published prior to the international filing date but later and document member of the same document member	ne patent family
does does does than ate of the a way SEPTE. The same and machine and commissione Box PCT	amount published prior to the international filling date but later and document member of the same actual completion of the international search. Date of mailing of the international search alling address of the ISA/US alling address of the ISA/US are of Patents and Trademarks D.C. 20231	ne patent family

International application No. PCT/IL01/00267

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
Please See Extra Sheet.
1. X As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
+. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
·
Remark on Protest The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

International application No. PCT/IL01/00267

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-19 and 51-65, drawn to an anastomosis connector delivery system and a method of mounting an anastomosis connector.

Group II, claim(s) 20-43, drawn to a punch.

Group III, claim(s) 44-52, drawn to a catheter system.

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to an anastomotic connector delivery system and method, while Group II is directed to a punch. Group III is directed to a catheter system.

09/926/08

PATENT COOPERATION TREA

PCT

52.70 13 SEP 208

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01360	FOR FURTHER ACTION		on of Transmittal of International xamination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/month/year) Priority date (day/month/year)		
PCT/IB00/00310	20 March 2000 (20.03.2000)		19 March 1999 (19.03.1999)
International Patent Classification (IPC)	or national classification and IPC		
IPC(7): A61B 17/08 and US Cl.: 606/13	,221		<u> </u>
Applicant			
BY-PASS, INC.			
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.			
2. This REPORT consists of	a total of 4 sheets, including	this cover shee	et.
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).			
These annexes consist of a	total of sheets.		
3. This report contains indica	tions relating to the following	items:	
I Basis of the repo	ort		
II Priority			
III Non-establishme	ent of report with regard to no	velty, inventive	step and industrial applicability
IV Lack of unity of	invention		
V Reasoned statem	V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
VI Certain documer		ang such succ	
VIII Certain observations on the international application			
			
Date of submission of the demand	Date	of completion	of this report
19 October 2000 (19.10.2000)	10.0		
		ugust 2001 (03.0	6.2001)
Name and mailing address of the IPEA/U Commissioner of Patents and Trademark		orized officer	
Box PCT Washington, D.C. 20231 Foogsimile No. (702) 205 2220			
Facsimile No. (703)305-3230 Telephone No. 703-308-0858 Form PCT/IPEA/409 (cover sheet)(July 1998)			08-0858

Internation application	No.
PCT/IB00/00310	

I.	Bas	is of the report
1.	With	regard to the elements of the international application:*
		the international application as originally filed.
	\boxtimes	the description:
		pages 1-21 as originally filed
İ		pages NONE , filed with the demand
		pages NONE , filed with the letter of
	\boxtimes	the claims:
		pages 22-26 , as originally filed pages NONE , as amended (together with any statement) under Article 19
		pages 27-29 , filed with the demand
		pages NONE , filed with the letter of
	X	the drawings:
		pages 1-25, as originally filed
		pages NONE , filed with the demand
		pages NONE , filed with the letter of
		the sequence listing part of the description:
		pages NONE , as originally filed
		pages NONE , filed with the demand pages NONE , filed with the letter of .
2.	Witl	regard to the language, all the elements marked above were available or furnished to this Authority in the
	lang	uage in which the international application was filed, unless otherwise indicated under this item.
	Thes	e elements were available or furnished to this Authority in the following language English which is:
		the language of a translation furnished for the purposes of international search (under Rule23.1(b)).
		the language of publication of the international application (under Rule 48.3(b)).
	Ш	the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).
3.	With inter	n regard to any nucleotide and/or amino acid sequence disclosed in the international application, the national preliminary examination was carried out on the basis of the sequence listing:
		contained in the international application in printed form.
		filed together with the international application in computer readable form.
		furnished subsequently to this Authority in written form.
		furnished subsequently to this Authority in computer readable form.
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the
		international application as filed has been furnished.
		The statement that the information recorded in computer readable form is identical to the written sequence listing
		has been furnished.
4.		The amendments have resulted in the cancellation of:
		the description, pages NONE
		the claims, Nos. NONE
		the drawings, sheets/fig NONE
5.	\square	This report has been established as if (some of) the amendments had not been made, since they have been considered to go
٥.	لاعا	beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**
thi:	repo	cement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in rt as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
	iviy I	eplacement sheet containing such amendments must be referred to under item 1 and annexed to this report.



Internati application No.	
PCT/IB00/00310	

III. Non-establishment of opinion with regard t novelty, inventive step and industrial applicability			
 The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of: 			
	the entire international application,		
\bowtie	claims Nos. <u>62 and 73</u>		
becau	use:		
	the said international application, or the said claim Nos relate to the following subject matter which does not require international preliminary examination (specify):		
	the description, claims or drawings (indicate particular elements below) or said claims Nos are so unclear that no meaningful opinion could be formed (specify):		
	the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed.		
\boxtimes	no international search report has been established for said claims Nos. 62 and 73		
2. A me	aningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid mee listing to comply with the standard provided for in Annex C of the Administrative Instructions:		
	the written form has not been furnished or does not comply with the standard.		
	the computer readable form has not been furnished or does not comply with the standard.		

Form PCT/IPEA/409 (Box III) (July 1998)



Internat application No. PCT/IB00/00310

V.	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step	r industrial applicability
	citations and explanations supporting such statement	

1. STATEMENT

 Novelty (N)
 Claims 1-58,63-72 / Sp-61
 YES / NO

 Inventive Step (IS)
 Claims 1-58,63-72 / Sp-61
 YES / Claims 59-61

 Industrial Applicability (IA)
 Claims 1-61,63-72 / Sp-61
 YES / NO

 Industrial Applicability (IA)
 Claims 1-61,63-72 / Sp-61
 YES / NO

2. CITATIONS AND EXPLANATIONS -----NEW CITATIONS-----

US 3,908,662 A (RAZGULOV ET AL) 30 SEPTEMBER 1975, see entire document.

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft eversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68-70 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

Form PCT/IPEA/409 (Box V) (July 1998)

10

25

- A connector according to claim 45, wherein all of said phura FAMIS 11 9 Oct 2000 55. constant width.
- A connector according to claim 45, comprising a strain dissipation element at a point of 56. connection of at least one of said elements and a spike element to which said ring segment is attached.
 - 57. A connector according to claim 56, wherein said strain dissipation element comprises a thickening of said axially spaced element.
 - A connector according to claim 57, wherein said thickening defines an aperture. 58.
- 59. A method of everting a blood vessel, comprising: engaging a tip of said vessel at a plurality of points around its circumference; inverting said tip by inverting said points; and 15 pulling said inverted points towards a distal end of said blood vessel.
 - б0. A method according to claim 59, wherein said plurality comprises at least four points.
- 20 61. A method according to claim 59, wherein said engaging comprises engaging using forceps and wherein said inverting comprises rotating said forceps.
 - 62. A method according to any of claims 59-61, wherein said pulling comprises pulling different ones of said points different amounts.
 - 63. Apparatus for graft eversion of a graft over a shaft having a tip, comprising: a handle for engaging said shaft;
 - a plurality of forceps arranged to engage a tip of said graft where it protrudes form said shaft; and
- 30 a plurality of joints, each one associated with one of said forceps, for rotating said forceps pulling a tip of each of said forceps axially along said shaft.
 - 64. A method of measuring a graft size, comprising:

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mounting a tip of said graft on two extensions, one extension tale programd 2000 one extension coupled to a handle;

manipulating said handle such that said extensions separate;
reading a measurement on a scale coupled to said spring; and
selecting an anastomosis connector responsive to said read measurement.

- 65. A method according to claim 64, comprising further manipulating said hardle to stretch said graft tip.
- 10 66. A hole puncher, comprising:

a sharp tip for forming a puncture in a blood vessel;

a shaft having a varying diameter and having a depression formed therein for engaging a wall of said blood vessel, said diameter substantially matching a diameter of said tip at one end of the shaft, said diameter increasing away from said tip for a first distance and said diameter then defining a slope of diminishing diameter towards said depression; and

an outer tube mounted on said shaft and having an end, said outer tube having an inner diameter of said end that is in a range of diameters defined by said slope of diminishing diameters.

- 20 67. A puncher according to claim 66, wherein said end of said outer tube has a smaller outer diameter that a more proximal portion of said outer tube.
 - A puncher according to claim 66 or claim 67, wherein said diminishing diameter slope is obliquely arrange around said shaft.

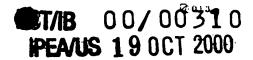
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- 69. A method of forming an oblique anastomosis connector, comprising: providing a non-oblique anastomosis connector; mounting said connector in a restraint;
- manipulating said restraints to deform said connector to a desired degree of obliqueness; and

heat-treating said connector after said manipulation, to maintain said distortion.

70. A method according to claim 69, comprising heat-treating said connector prior to said mounting, to train a deformation of a spike portion of said connector.

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- 71. A side mounted delivery system, comprising:
 - a handle including an opening in its side;
 - a graft delivery tool adapted to fit through said opening; and
- a groove and projection mechanism slidably interconnecting said tool and said handle.
 - 72. A system according to claim 71, comprising a snap-lock mechanism for axially fixing said handle relative to said tool.
- 10 73. A method according to any of claims 59-61, wherein said points are inverted simultaneously.





From the INTERNATIONAL SEARCHING AUTHORITY

To: MAIER FENSTER

FENSIER & COMPANY PATENT

2 6 -12- 2000

FENSTER & Co.

ATTORNEYS, LTD.	FENSIER &		
POST OFFICE BOX 10256 PASSAGE ARECANA 17 SEP 2001	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION		
	(PCT Rule 44.1)		
	Date of Mailing (day/month/year) 05 SEP 2000		
Applicant's or agent's file reference	700		
088/01360	FOR FURTHER ACTION See paragraphs 1 and 4 below		
International application No.	International filing date		
PCT/IB00/00310	(day/month/year) 20 MARCH 2000		
Applicant	20 1124011 2000		
BY-PASS, INC.			
1. X The applicant is hereby notified that the international	search report has been established and is transmitted herewith.		
Filing of amendments and statement under Article. The applicant is entitled, if he so wishes, to amend to	the claims of the international application (see Rule 46):		
When? The time limit for filing such amendm	ents is normally 2 months from the date of transmittal of the more details, see the notes on the accompanying sheet.		
Where? Directly to the International Bureau of W	VIPO		
34, chemin des Colombei 1211 Geneva 20, Switzer	ttes		
Facsimile No.: (41-22) 740.14.35			
For more detailed instructions, see the notes on the accompanying sheet.			
2. The applicant is hereby notified that no international Article 17(2)(a) to that effect is transmitted herewith	search report will be established and that the declaration under		
3. With regard to the protest against payment of (an)	additional fee(s) under Rule 40.2, the applicant is notified that:		
the protest together with the decision thereon happlicant's request to forward the texts of both	as been transmitted to the International Bureau together with the a the protest and the decision thereon to the designated Offices.		
no decision has been made yet on the protest;	the applicant will be notified as soon as a decision is made.		
4. Further action(s): The applicant is reminded of the following	lowing:		
Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.			
Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).			
Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.			
Name and malling add an extra section and an extra	7		
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks	Authorized officer		
Box PCT Washington, D.C. 20231	ONATHAN GOLDBERG		
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0161		
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Porm PCT/ISA/220 (July 1998) *

(See notes on accompanying sheet)

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/01360	FOR FURTHER ACTION	see Notification of (Form PCT/ISA/22)	Transmittal of International Search Report O) as well as, where applicable, item 5 below.
International application No.	International filing date	_	
PCT/IB00/00310	20 MARCH 2000	· (my///wimbyettt)	(Earliest) Priority Date (day/month/year) 19 MARCH 1999
Applicant BY-PASS, INC.			
,	ng dansmined to the intern	antonal Ruleau.	tority and is transmitted to the applicant
This international search report consist X It is also accompanied by a			port.
1. Basis of the report			
a. With regard to the language, the language in which it was filed	, unico outsiwisa inticaled i	uncer mis item	is of the international application in the
Authority (Rule 23.1(b)).	carried out on the basis of	a translation of the	international application furnished to this
b. With regard to any nurleotide was carried out on the basis of	and/or amino acid sequence the sequence listing:	e disclosed in the int	ternational application, the international search
contained in the internation	al application in written for	m.	
filed together with the inter	national application in com	putor readable form.	
furnished subsequently to the			
furnished subsequently to the	is Authority in computer re	eadable form.	
application as	the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.		
the statement that the informs furnished.	ution recorded in computer re		cal to the written sequence listing has been
2. Certain claims were found).	
3. Unity of invention is lacki	ng (See Box II).		
4. With regard to the title,			
X the text is approved as subm	nitted by the applicant.		
the text has been established	by this Authority to read :	as follows:	
5. With regard to the abstract,			
the text is approved as subm	itted by the applicant.		
the text has been established Box III. The applicant may, search report, submit comm	within one month from the	, by this Authority a date of mailing of th	s it appears in is international
6. The figure of the drawings to be p	ublished with the abstract is	Figure No. 1	_
X as suggested by the applican	i.		
because the applicant failed	to suggest a figure.		None of the figures.
because this figure better ch			
Form PCT/ISA/210 (first sheet) (bilv 19	200.4		

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

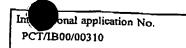
NEW ABSTRACT

An anastomosis connector comprises a plurality of ring segments (106), together defining a radially expandable ring-like shape (106) having a lumen, at least one pivot bar (114) coupled to at least one of said ring segments (106), at least one spike (109) mounted on said pivot bar (114), and rotatable around said pivot bar (114), wherein radial deformation of said ring-like shape (106) does not substantially directly affect the said spike (109) rotational position.

	<u>.</u>
Int	onal application No.
PCT	71B00/00310

A. CL	ASSIFICATION OF SUBJECT MATTER	
US CL	:A61B 17/08 :606/153, 221	
According	to International Patent Classification (IPC) or to both national classification a	nd IPC
D. FIE	LDS SEARCHED	
U.S. :	documentation searched (classification system followed by classification symb	ols)
Document	ation searched other than minimum documentation to the extent that such docum	ents are included in the fields searched
BRS	data base consulted during the international search (name of data base and, wh	nere practicable, search terms used)
	crms: anastomosis, \$lock\$ or mating, teeth or ratchet\$2, ring, strut	
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant	passages Relevant to claim N
Y	US 4,214,586 A (MERILE) 29 July 1980, whole docume	
Y	US 4,657,019 A (WALSH et al.) 14 April 1987, whole	document. 1-65
Y	US 5,234,448 A (WHOLEY et al.) 10 August 199 document.	93, whole 1-65
Y	US 5,234,447 A (KASTER et al.) 10 August 1993, whole	document. 65-72
Y	US 5,695,504 A (GIFFORD, III et al.) 09 December 19 document.	97, whole 65-72
4	US 4,366,819 A (KASTER) 04 January 1983.	1-65
X Furthe	er documents are listed in the continuation of Box C. See patent fan	nily annex
\" docu	of the state of th	shed after the international filing date or priority in with the application but cited to understand the intention
document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other		
special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document referring to an oral disclosure, use, exhibition or other means		
	niority date claimed "&" document member of	the same patent family
ate of the ac	ctual completion of the international search Date of mailing of the international	
07 AUGUS	T 2000 05 SEP 200	
ame and ma Commissioner Box PCT	iling address of the ISA/US r of Patents and Trademarks Authorized officer	Nintes
Washington, I csimile No.	(P	ERG
CSIMILE NO.	(703) 305-3230 Telephone No. (703) 3	





Category*	Citation of document, with indication, where appropriate, of the relevant	nt passages	Relevant to claim 1	 10.
\	US 3,908,662 A (RAZGULOV et al.) 30 September 19	75.	1-65	
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From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

MAIER FENSTER

FENSTER & COMPANY PATENT ATTORNEYS, LTD.

P.O. BOX 10256

PETACHTIKVA. ISRAEL

PTO/PET Rec'd 17 SEP 200

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

(PCT Rule 71.1)

Date of Mailing (day/month/year)

Applicant's or agent's file reference

088/01360

Applicant

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/IB00/00310

20 March 2000 (20.03.2000)

19 March 1999 (19.03.1999)

BY-PASS, INC.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any amnexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume !] of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT

Washington, D.C. 20231

Facsimile No. (703)305-3230 Form PCT/IPEA/416 (July 1992)

Telephone No. 703-308-0858

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's fi	le reference			
088/01360 International application		FOR FURTHER ACTION	1 returningly i	ion of Transmittal of International Examination Report (Form PCT/IPEA/416
	Inte	manional filing date (day/mor	th/year)	Priority date (day/month/year)
PCT/IB00/00310	20 }	March 2000 (20.03.2000)		į.
International Patent Class	sification (IPC) or nat	March 2000 (20.03.2000) ional classification and IPC	· · · · · · · · · · · · · · · · · · ·	19 March 1999 (19.03.1999)
IPC(7): A61B 17/08 and	US C1 - 606/12 221			
Applicant	05 CI 006/13,221			
BY-PASS. INC.				
DITAMS, INC.				
1. This internal	ional prolimina			
Examining A	uthority and is tran	xamination report has been is mitted to the applicant ac	prepared by	this International Preliminary
2. This REPOR	T consists of a tora	of sheets, including t	his cover shee	20
This ros	Ort is also			
which h	ort is also accompa	nied by ANNEXES, i.e.,	sheets of the o	description, claims and/or drawings
before t	ave been amenged a	and are the basis for this re	or solbne mode	description, claims and/or drawings heets commining rectifications made
		A	of the Admir	heets commining rectifications made nistrative Instructions under the PCT).
These annexe	s consist of a total	of 2 sheets.		== 31).
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111 🔯 1001	1-establishment of r	eport with regard to novel	ty, inventive s	step and industrial applicability
IV Lac	k of unity of invent	ion	-	and marginal applicability
				
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	ain documents cited		g such statem	ent
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		Date of	completion of	this report
19 October 2000 (19.10.2000)				
		OJ Augus	t 2001 (03.08.2	2001)
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Washington D.C. 2023	1	Carv E.	O'Comor (47
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n PCT/IPEA/409 (cover s	heet)(July 1998)	Telephone	No. 703-308	-0858

INTERNATIONAL PRELI	RY	EXAMINATION REPORT
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Interna	application No.	
PCT/IBOO/OC		

I.	Basi	is of the report
_		-
1.		regard to the elements of the international application:* the international application as originally filed.
	\bowtie	
		the description: pages 1:21 as originally filed
		pages 1-21 as originally filed pages NONE, filed with the demand
		pages NONE , filed with the letter of
	\square	the claims:
		· · · · · · · · · · · · · · · · · · ·
		pages NONE , as amended (together with any statement) under Article 19 pages 27-29 , filed with the demand
		pages NONE , filed with the letter of
	\boxtimes	the drawings:
		pages 1-25 as originally filed
		pages NONE , filed with the demand
		pages NONE, filed with the letter of
		the sequence listing part of the description:
		pages NONE as originally filed
		pages NONE , filed with the demand
7	11.554L	pages NONE , filed with the letter of
4.	lanmı WIM	regard to the language, all the elements marked above were available or furnished to this Authority in the
	These	tage in which the international application was filed, unless otherwise indicated under this item. The elements were available or furnished to this Authority in the following language English which is:
		the language of a translation furnished to this Although in the following language English which is:
	\Box	the language of a translation furnished for the purposes of international search (under Rule 23.1(b)), the language of publication of the international application (under Rule 48.3(b)).
	\Box	the language of the conglosion for international application (under Rule 48.3(b)).
		the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3.	With	regard to any nucleofide and/or amino acid sequence disclosed in the international application, the
1		y chammadod was carried did on the basis of the sequence listing:
	<u> </u>	contained in the international application in printed form.
	╡	filed together with the international application in computer readable form.
	- '	furnished subsequently to this Authority in written form.
ļ	'	furnished subsequently to this Authority in computer readable form.
l		The statement that the subsequently furnished written required limited decided
ı		Translated has been ministed.
į		The statement that the information recorded in computer readable form is identical to the written sequence listing
_	1	has been furnished.
4. [_] :	The amendments have resulted in the cancellation of:
		the description, pages NONE
	Ì	the claims, Nos. NONE
	Ì	the drawings, sheets/fig NONE
5. [√	
2		his report has been established as if (some of) the amendments had not been made, since they have been considered to go
r Re	place	ment sheets which have been firmished to the residue Office
his i	ероп	ment sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
A	ny rep	placement sheet containing such amendments must be referred to under item 1 and annexed to this report.
		PFA/400 (Pay 1) (Int., 1000)

INTERNATIONAL PRELI	RY EXAMINATION REPORT
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ı	Interna	application No.	
ı		PP=====::	
ı	PCT/IB00/	20031.0	
Į	FC1/1B00/	00310	

M. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), to be industrially applicable have not been and will not be examined in respect of:						
the entire international application,						
Claims Nos. 62 and 73						
because:						
the said international application, or the said claim Nos relate to the following subject matter which do not require international preliminary examination (specify):						
the description, claims or drawings (indicase particular elements below) or said claims Nos are so unche that no meaningful opinion could be formed (specify):						
the claims, or said claims Nos are so inadequately supported by the description that no meaningful						
no international search report has been established for said claims Nos. 62 and 73						
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Apper C of the Administration						
The state of the Authinistian of the Authinist						
the written form has not been furnished or does not comply with the standard.						
the computer readable form has not been furnished or does not comply with the sandard.						
Form PCT/IPEA/409 (Box III) (July 1998)						



Internal pplication No. PCT/IBC 310

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelry (N)	Claims 1-58,63-72	YES
·	Claims 59-61	NO
Inventive Step (IS)	Claims 1-58.63-72	YES
	Claims 59-61	NO
Industrial Applicability (IA)	Claims 1-61.63-72	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS NEW CITATIONS

US 3,908,662 A (RAZGULOV ET AL) 30 SEPTEMBER 1975, see entire document.

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3.908.662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft eversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68-70 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

\mathbf{PCT}





INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(51) International Patent Classification 7:		THE PATENT COOPERATION TREATY (PCT)
A61B 17/08	AI	(11) International Publication Number: WO 00/56228
	121	(43) International Publication Date: 28 September 2000 (28.09.00)
(21) International Application Number: PCI	T/IB00/0031	Petach Tikva (IL), ZIMET, Nachman III (II)
(22) International Filing Date: 20 March 200	00 (20.03.00	5, 69016 Tel Aviv (TL).
i	((74) Agente EUNICOTTO

(74) Agents: FENSTER, Paul et al.; Fenster & Company Parent Attorneys, Ltd., P.O. Box 10256, 49002 Petach Tikva (IL).

(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FL, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SI, TI, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TI, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CJ, CM, GA, GN. GW. ML, MR, NE, SN, TD, TG).

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application

ÙS PCT/IL99/00674 (CIP) Filed on 9 December 1999 (09.12.99)

19 March 1999 (19.03.99)

8 December 1999 (08.12.99)

9 December 1999 (09.12.99)

30 May 1999 (30,05,99)

30 May 1999 (30.05.99)

(71) Applicant (for all designated States except US): BY-PASS. INC. [US/US]; 40 Ramland Road, Orangeburg, NY 10962 (US).

(72) Inventors, and

(30) Priority Data: 129067

PCT/IL99/00284

PCT/IL99/00285

PCT/IL99/00670

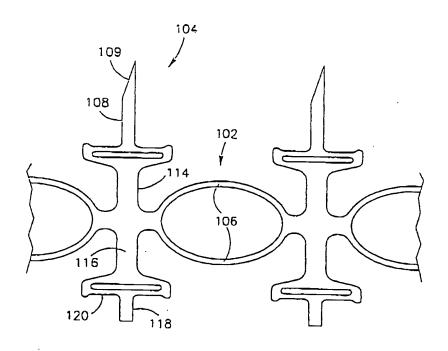
PCT/IL99/00674

(75) Inventors/Applicants (for US only): LOSHAKOVE, Amir [IL/IL]; P.O. Box 204, 42860 Moshav Burgeta (IL). KILEMNIK Ido [IL/IL]; Nordau Street 35, 46585 Horzelia (IL). KEREN, Dvir [IL/IL]; Harav Kook Street 31, 49315

Published

With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: LOW PROFILE ANASTOMOSIS CONNECTOR



(57) Abstract

An anastomosis connector comprises a plurality of ring segments (106), together defining a radially expandable ring-like shape (106) having a lumen; at least one pivot bar (114) coupled to at least one of said ring segments (106); at least one spike (109) mounted on said pivot bar (114) and rotatable around said pivot bar (114), wherein radial deformation of said ring-like shape (106) does not substantially

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CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
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PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

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FENSTER, Paul Fenster & Company Patent Attorneys, Ltd. P.O. Box 10256 49002 Petach Tikva ISRAEL

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Applicant's or agent's file reference 088/01360

International application No. PCT/IB00/00310

International filing date (day/month/year)
20 Warch 2000 (20.03.00)

Priority date (day/month/year) 19 March 1999 (19.03.99)

IMPORTANT NOTICE

Applicant

BY-PASS, INC. et al

 Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AG,AU,DZ,KP,KR,US

1

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

- 2. The following designated Offices have waived the requirement for such a communication at this time:
 - AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW applicant to furnish a copy of the international application (Rule 49.1(a-bis)).
- 3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 September 2000 (28.09.00) under No. WO 00/56228

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 18 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

J. Zahra

Telephone No. (41-22) 338,83,38

Facsimile No. (41-22) 740.14.35

NOTICE:INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

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The applicant is hereby notified that; at the time of establishment of this Notice; the time limit under Rule 46-il for making amendments under Article 19 has not yet expired and the hyternational Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

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- 55. A connector according to claim 45, wherein all of said plurality of elements have a constant width.
- 56. A connector according to claim 45, comprising a strain dissipation element at a point of connection of at least one of said elements and a spike element to which said ring segment is attached.
  - 57. A connector according to claim 56, wherein said strain dissipation element comprises a thickening of said axially spaced element.
  - 58. A connector according to claim 57, wherein said thickening defines an aperture.
- A method of everting a blood vessel, comprising:
   engaging a tip of said vessel at a plurality of points around its circumference;
   inverting said tip by inverting said points; and
   pulling said inverted points towards a distal end of said blood vessel.
  - 60. A method according to claim 59, wherein said plurality comprises four points.
- 20 61. A method according to claim 59, wherein said engaging comprises engaging using forceps and wherein said inverting comprises rotating said forceps.
  - 62. A method according to any of claims 59-61, wherein said pulling comprises pulling different ones of said points different amounts.
  - 63. Apparatus for graft eversion of a graft over a shaft having a tip, comprising: a handle for engaging said shaft;
  - a plurality of forceps arranged to engage a tip of said graft where it protrudes form said shaft; and
- a plurality of joints, each one associated with one of said forceps, for rotating said forceps pulling a tip of each of said forceps axially along said shaft.
  - 64. A method of measuring a graft size, comprising:

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mounting a tip of said graft on two extensions, one extension coupled to a spring and one extension coupled to a handle;

manipulating said handle such that said extensions separate; reading a measurement on a scale coupled to said spring; and selecting an anastomosis connector responsive to said read measurement.

- 65. A method according to claim 64, comprising further manipulating said handle to stretch said graft tip.
- 10 66. A hole puncher, comprising:

a sharp tip for forming a puncture in a blood vessel;

a shaft having a varying diameter and having a depression formed therein for engaging a wall of said blood vessel, said diameter substantially matching a diameter of said tip at one end of the shaft, said diameter increasing away from said tip for a first distance and said diameter then defining a slope of diminishing diameter towards said depression; and

an outer tube mounted on said shaft and having a tip, said outer tube having an inner diameter of said tip that is in a range of diameters defined by said slope of diminishing diameters.

- 20 67. A puncher according to claim 66, wherein said tip of said outer tube has a smaller outer diameter that a more proximal portion of said outer tube.
  - A puncher according to claim 66 or claim 67, wherein said diminishing diameter slope is obliquely arrange around said shaft.

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- 69. A method of forming an oblique anastomosis connector, comprising: providing a non-oblique anastomosis connector; mounting said connector in a restraint;
- manipulating said restraints to deform said connector to a desired degree of obliqueness; and

heat-treating said connector after said manipulation, to maintain said distortion.

70. A method according to claim 69, comprising heat-treating said connector prior to said mounting, to train a deformation of a spike portion of said connector.

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71. A side mounted delivery system, comprising:

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- a handle including an opening in its side;
- a graft delivery tool adapted to fit through said opening; and
- a groove and projection mechanism slidably interconnecting said tool and said handle.
- 72. A system according to claim 71, comprising a snap-lock mechanism for axially fixing said handle relative to said tool.

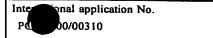
Intern applicati n No. PCT. 0310

#### **CLASSIFICATION OF SUBJECT MATTER** IPC(7) :A61B 17/08 US CL :606/153, 221 According to International Patent Classification (IPC) or to both national classification and IPC **FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) U.S.: 606/153, 221 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Search Terms: anastomosis, \$lock\$ or mating, teeth or ratchet\$2, ring, strut **DOCUMENTS CONSIDERED TO BE RELEVANT** Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Category* US 4,214,586 A (MERILE) 29 July 1980, whole document. Y 1-65 US 4,657,019 A (WALSH et al.) 14 April 1987, whole document. 1-65 US 5,234,448 A (WHOLEY et al.) 10 August 1993, whole 1-65 Y document. US 5,234,447 A (KASTER et al.) 10 August 1993, whole document. 65-72 Y US 5,695,504 A (GIFFORD, III et al.) 09 December 1997, whole Y 65-72 document. US 4,366,819 A (KASTER) 04 January 1983. 1-65 Α X Further documents are listed in the continuation of Box C. See patent family annex. later document published after the international filing date or priority date and not in conflict with the application but cited to understand the Special categories of cited documents: -Adocument defining the general state of the art which is not considered principle or theory underlying the invention to be of particular relevance document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "X" earlier document published on or after the international filing date when the document is taken alone document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another cutation or other document of particular relevance; the claimed invention cannot be special reason (as specified) considered to involve an inventive step when the document is combined with one or more other such documents, such combination document referring to an oral disclosure, use, exhibition or other means being obvious to a person skilled in the art ъ. document published prior to the international filing date but later than the priority date claimed document member of the same patent family Date of mailing of the international search report Date f the actual completion of the international search 05 SEP 2000 **07 AUGUST 2000** Authorized officer Name and mailing address of the ISA/US Commissioner of Patents and Trademarks ONATHAN GOLDBERG Washington, D.C. 20231

(703) 308-0161

Telenhone No.

Facsimile No.



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tion). DOCUMENTS CONSIDERED TO BE RELEVANT		
Citation of document, with indication, where appropriate, of the relev	ant passages	Relevant to claim No.
US 3,908,662 A (RAZGULOV et al.) 30 September 19	975.	1-65
		·
		·
	Citation of document, with indication, where appropriate, of the relev	tion). DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages  US 3,908,662 A (RAZGULOV et al.) 30 September 1975.

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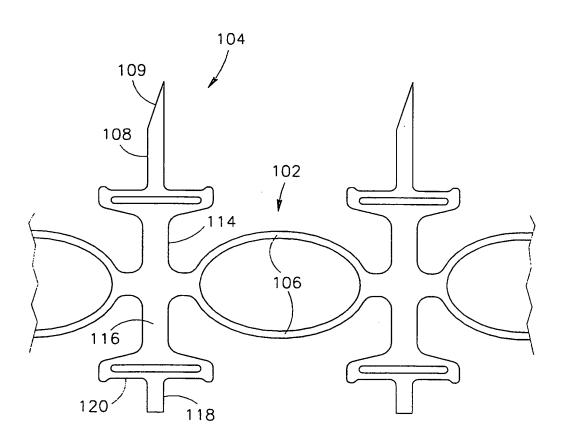
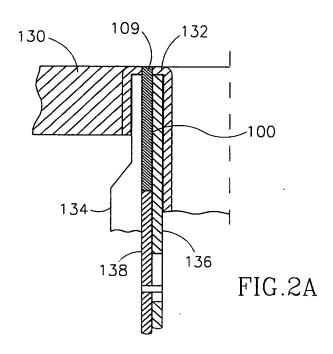
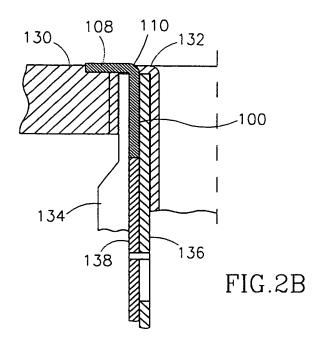


FIG.1

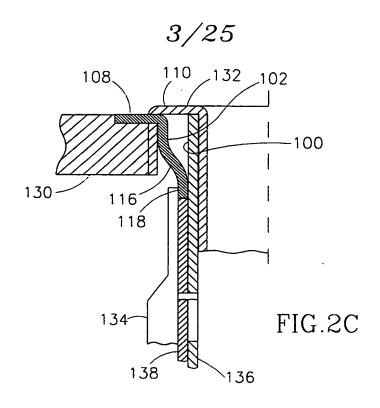
WO 00/56228 PCT/IB00/00310

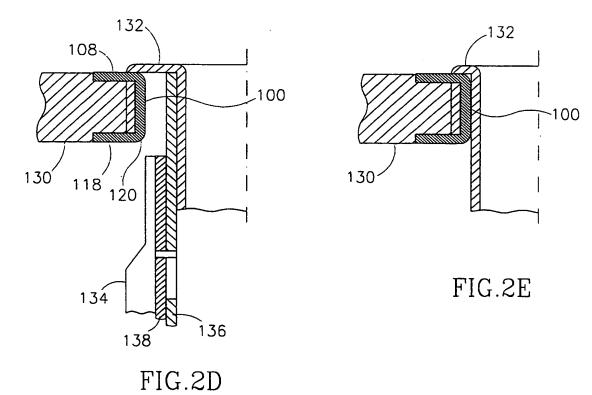
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C16 Rec'd PCT/PTO SEP 1 7 2001

Application No. PCT/IB00/00310

Applicant: By-pass Inc. et al.

Filed: March 20, 2000

Title: Low Profile Anastomosis Connector

Examiner: Cary E. O'Connor



#### RESPONSE TO WRITTEN OPINION

This letter is in response to a written opinion dated February 22, 2001. Claims 59-61 of application No. PCT/IB00/00310; "Low Profile Anastomosis Connector" stand rejected under PCT Article 33(2) as being anticipated by RAZGULOV et al. (3,908,662).

In the invention as claimed in claim 59, the points are inverted after being engaged by the blood vessel.

For example, in Fig. 1, points 109 and 118 are on the same axial plane as component 102. In Fig. 2A point 109 is unbent as it comes in contact with blood vessel 132. Further, the invention as claimed in claim 59 requires that the tip be inverted by inverting the points.

In contrast US 3,908,622, Figs. 13-15 demonstrate a plurality of points that are already inverted when they engage the blood vessel. As seen in Fig. 15, the inverted points are not inverted further during the loading of the blood vessel.

The following corrections of typographic errors and omissions of numbering in Figs. 1, 2A-E have been made according to representations in the application text.

- In Fig. 1, number 110 has been added, pointing to the upper pivot bar.
- In Fig. 2A, number 110 has been added, pointing to the upper pivot bar, number 120 has been added, pointing to the lower pivot bar and number 118 has been added, pointing to the lower spike.
- In Fig. 2B, number 120 has been added, pointing to the lower pivot bar and number 118 has been added, pointing to the lower spike.
- In Fig. 2C number 110 has been corrected to point to the upper pivot bar number 100 has been corrected to point to the connector and number 120 has been added, pointing to the lower pivot bar.
- In Fig. 2D, number 110 has been added, pointing to the upper pivot bar.



In Fig. 2E, number 110 has been added, pointing to the upper pivot bar, number 120 has been added, pointing to the lower pivot bar, number 108 has been added, pointing to the upper spike and number 118 has been added, pointing to the lower spike.

Claims 62 and 73 stand objected to for improper multiple dependent claims under PCT rule 6.4(a).

PCT rule 6.4(a) indeed states, "Multiple dependent claims shall not serve as a basis for any other multiple dependent claim." Both claims 62 and 73 are dependent on claims 59-61 which are either independent (claim 59), or singly dependent on claim 59 (claims 60 and 61). Thus claims 62 and 73 are in proper form.

In view of the above remarks and amendments, a positive IPER is respectfully awaited.

A copy of this response is being forwarded to you by courier.

Respectfully Submitted,

aul Fenster

Paul Fenster

Agent for the Applicant

From the INTERNATIONAL PRELIMINARY EXAMININO	G AUTHORITY		FILE COPY		
To: MAIER FENSTER FENSTER & COMPANY PATENT ATTORNEY P.O. BOX 10256		PCT			
PETACH TIKVA, ILX 49002			WRITTEN OPINION		
			(PCT Rule 66)		
		Date of Mailing (day/month/year)			
Applicant's or agent's file reference		REPLY DUE			
088/01360			within 2 months/days from the above date of mailing		
International application No. International	ional filing date (de	ay/month/year)	Priority date (day/month/year)		
PCT/IB00/00310 20 Marc	ch 2000 (20.03.200	00)	19 March 1999 (19.03.1999)		
International Patent Classification (IPC) or both na	ational classificatio	on and IPC			
IPC(7): A61B 17/08 and US Cl.: 606/13,221			<u></u>		
Applicant					
BY-PASS, INC.					
		<u> </u>			
1. This written opinion is the <u>first</u> (first,	, etc,) drawn by thi	is International Pro	eliminary Examining Authority.		
2. This opinion contains indications relati	ing to the following	g items:	·		
v 🖂 p					
I Basis of the opinion					
II Priority					
III Non-establishment of opini	on with regard to r	novelty, inventive	step and industrial applicability		
IV Lack of unity of invention			:		
V Reasoned statement under locations and explanations s		_	ty, inventive step or industrial applicability;		
VI Certain documents cited	supporting such sta	nement			
VII Certain defects in the intern	national application	n			
VIII Certain observations on the					
<del></del>					
3. The applicant is hereby invited to rep	• -	annliaant may haf	ore the expiration of that time limit_request		
When? See the time limit indic this Authority to grant			ore the expiration of that time limit, request		
How? By submitting a written For the form and the la	n reply, accompani anguage of the ame	ied, where approp endments, see Rul	riate, by amendments, according to Rule 66.3. es 66.8 and 66.9.		
Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6					
If no reply is filed, the international p	preliminary examin	nation report will b	be established on the basis of this opinion.		
The final date by which the internation examination report must be established.	nal preliminary d according to Rule	e 69.2 is: <u>19 July</u>	2001 (19.07.2001)		
Name and mailing address of the IPEA/US		Authorized office	T		
Commissioner of Patents and Trademarks Box PCT		Cary E. O'Connor			
Washington, D.C. 20231 Facsimile No. (703)305-3230		Telephone No. 7			
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#### WRITTEN OPINION

International application No.

PCT/IB00/00310

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I.	Basis of the opinion	n mene oon n
1.	With regard to the elements of the international application:*	
	the international application as originally filed	
	the description:	
	pages 1-21 , as originally filed	
	pages NONE , filed with the demand	
	pages NONE, filed with the letter of	·
	the claims:	·
	pages 22-26, as originally filed	
	pages NONE , as amended (together with any statement) under Article 19	
	pages 27-29 , filed with the demand	
	pages NONE , filed with the letter of	<del></del> '
	the drawings:	
	pages 1-25, as originally filed	
	pages NONE , filed with the demand	
	pages NONE, filed with the letter of	_·
	the sequence listing part of the description:	•
	pages NONE , as originally filed	
	pages NONE , filed with the demand	
	pages NONE, filed with the letter of	<b>-</b> •
2.	With regard to the <b>language</b> , all the elements marked above were available or furnished to language in which the international application was filed, unless otherwise indicated under the These elements were available or furnished to this Authority in the following language <u>Engli</u>	his item.
	the language of a translation furnished for the purposes of international search (under I	Rule23.1(b)).
	the language of publication of the international application (under Rule 48.3(b)).	
	the language of the translation furnished for the purposes of international preliminary	examination(under Rules
	55.2 and/or 55.3).	·
3.	With regard to any nucleotide and/or amino acid sequence disclosed in the international a opinion was drawn on the basis of the sequence listing:	pplication, the written
	contained in the international application in printed form.	
	filed together with the international application in computer readable form.	
	furnished subsequently to this Authority in written form.	
	furnished subsequently to this Authority in computer readable form.	
	The statement that the subsequently furnished written sequence listing does not go beyon	ond the disclosure in the
	international application as filed has been furnished.	
	The statement that the information recorded in computer readable form is identical to t has been furnished.	he written sequence listing
4.	<b>5</b> 7	
	the description, pages NONE	•
	the claims, Nos. NONE	
	the drawings, sheets/fig NOE	
5.	This opinion has been drawn as if (some of) the amendments had not been made, since they have beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).	e been considered to go
	Replacement sheets which have been furnished to the receiving Office in response to an invitation under	r Article 14 are referred to in
thi	is opinion as "originally filed."	

#### WRITTEN OPINION

International application No.
PCT/IB00/00310

FILE COPY

WRITENOFINION	PCT/IB00/00310			
III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:				
the entire international application,				
claims Nos. 62 and 73				
because:				
the said international application, or the said claim Nos not require international preliminary examination (specify):	relate to the following	g subject matter which does		
·	•			
the description, claims or drawings (indicate particular elements below) or said claims Nos. 62 and 73 are so unclear that no meaningful opinion could be formed (specify):				
Claims 62 and 73 are improper multiple dependent claims under PCT rule 6.4(a).				
		•		
the claims, or said claims Nos are so inadequately support opinion could be formed.	rted by the descriptio	n that no meaningful		
no international search report has been established for said claim	ns Nos			
2. A written opinion cannot be drawn due to the failure of the nucleotide with the standard provided for in Annex C of the Administrative Instru		equence listing to comply		
the written form has not been furnished or does not comply with the standard.				

#### WRITTEN OPINION

International application No PCT/IB00/00310

V.	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1. STATEMENT		
Novelty (N)	Claims 1-58, 63-72	YES
	Claims <u>59-61</u>	NO
Inventive Step (IS)	Claims 1-61,63-72	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims NONE	YES
	Claims NONE	NO

#### 2. CITATIONS AND EXPLANATIONS

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft eversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68 and 69 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

document.

1-58 63-72 0b 02,127 (69-6)